Customer No.: 07278 Docket No.: 03269/8200177-000

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent No. 5,614,560

Inventors: Stuart A. LIPTON

Assignee: Children's Medical Center Corporation

Title: METHOD OF PREVENTING NMDA RECEPTOR-MEDIATED NEURONAL

**DAMAGE** 

Issue Date: March 25, 1997

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## WITHDRAWAL OF CONSENT OF NDA HOLDER

Mail Stop Patent Ext. Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Forest Laboratories, Inc. ("Forest"), the holder of NDA 21-487, which was approved October 16, 2003 and is the first marketing approval for memantine (NAMENDA<sup>TM</sup>), hereby withdraws any previous consent or authorization, either express or implied, for Children's Medical Center Corporation ("CMCC") to rely on the regulatory review period for NAMENDA<sup>TM</sup> in support of the pending Application for Extension of Patent Term of CMCC's U.S. Patent No. 5,614,560.

A communication was filed by CMCC on June 12, 2007, revoking any agency, authority or consent to Merz Pharma GmbH & Co. KGaA ("Merz") or Forest to act on CMCC's behalf with regard to any application for extension of the term of the '560 patent under 35 U.S.C. § 156.

The Application for Extension of Patent Term of the '560 patent was filed concurrently with an Application for Extension of Patent Term of U.S. Patent No. 5,061,703. Both applications were filed by Forest on December 9, 2003, and are based upon the same regulatory review period - i.e., the regulatory review period for memantine hydrochloride (NAMENDA<sup>TM</sup>). Today, pursuant to 37 C.F.R. 1.785(b), Forest has filed an Election of Application for Extension of Patent Term in which Forest has elected the Application for Extension of Patent Term of U.S. Patent No. 5,061,703. A copy of the Election is attached.

Dated: June 15, 2007

Respectfully submitted,

Adda G. Gogoris

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